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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

Shionogi & Co., Ltd., a Japanese company,

Plaintiff,

v.

InterMune, Inc., a Delaware corporation,

Defendant.

Case No. 3:12-cv-03495-EDL

REPLY IN SUPPORT OF SHIONOGI'S MOTION TO COMPEL

Date: **January 18, 2012**
Time: **3:30 p.m.**
Judge: **The Honorable Elizabeth D. Laporte**

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I. INTRODUCTION

InterMune concedes that nearly four months into a nine-and-a-half-month discovery period, it has not substantively answered a single interrogatory and has produced almost exclusively documents that Shionogi already had.[1] And, although InterMune attempts to shift the Court's attention to the trial date, the parties have a mediation scheduled for February, and the fact discovery cut-off for this litigation is six months away—July 5, 2013. The discovery schedule, to which InterMune stipulated, leaves very little time for follow-up discovery, and was predicated on efficient responses, which is why Shionogi filed its first set of discovery requests the day discovery opened.

InterMune has spent the first three-and-a-half months of the discovery period stonewalling Shionogi's discovery. This motion became necessary because InterMune would not agree to search terms for its document review and production. InterMune has not disclosed when it began its review or when it assembled the 20-attorney review team that it represents is now active, and its prior statements suggest that neither commenced until Shionogi filed this motion. Despite maintaining its burden objection for certain search terms, InterMune has not provided unique hit rates or responsiveness rates necessary to substantiate the objection. Further, InterMune does not dispute that it would not even estimate when it expected to produce documents until December 18, 2012, three months after receiving Shionogi's discovery requests. InterMune cannot demonstrate that its efforts have been reasonable when it does not even describe what efforts it has taken to ensure that it meets the July 5, 2013 discovery cut-off.

InterMune's primary argument in opposition to Shionogi's motion to compel is that the parties' discovery burdens must be equal, *i.e.*, if InterMune is required to run certain search terms, so must Shionogi. Shionogi disagrees, but after compiling the data needed to ascertain the burden of running those search terms, Shionogi has agreed to use the broader search terms for its review, subject to continuing evaluation of actual data, such as the responsiveness rates resulting from its

[1] InterMune's 261,000 page production (Opp. at 10:16), which was not forthcoming until after Shionogi filed its motion, appears to primarily consist of its MAA (the regulatory filing in which InterMune sought approval to sell Esbriet in the EU), which it provided to Shionogi more than a year ago. Prior to that, InterMune had only produced the two agreements under which it licensed Pirfenidone.

review. *See* Declaration of Katherine S. Ritchey in Support of Reply, Ex. 2 (hereinafter Ritchey Reply Decl.). Thus, the vast majority of InterMune's argument is moot—Shionogi is not asking InterMune to do anything it has not agreed to do. In fact, Shionogi has been reviewing documents since early November, and using a 20-person review team for more than a month to review 350,000 documents that are in its subject-specific folders. After completing its review of the subject-specific data, Shionogi expects to begin the review of hundreds of thousands of additional documents identified using search terms run in non-targeted electronic data (*i.e.* not foldered by the custodian).

InterMune also attempts to minimize the amount in controversy, with the implication that the burden of production is disproportionate to the stakes of this case. In fact, InterMune's own public statements suggest that it foresees billions of dollars in sales of Esbriet in Europe, which means that the royalties at issue may reach tens or hundreds of millions of dollars over the course of the parties' agreement. InterMune's repeated statements in its opposition that there is just $2 million at stake are not only inconsistent with its public projections of income in the EU, but is wrong in any event because it is based solely on the first two years of a ten-year agreement with an escalating royalty rate.

Finally, InterMune contends that a single interrogatory requesting the facts supporting a decision that it already has made is premature. InterMune's refusal to answer this single interrogatory until the end of discovery, is likely to prolong this litigation, rather than expedite it, because the response goes to the heart of this dispute.

Shionogi is entitled to timely substantive responses to discovery that it served nearly four months ago. The Court should compel InterMune to: (1) use Shionogi's requested search terms, (2) substantively respond to Interrogatory No. 2, and (3) complete its production in a time frame that ensures that the stipulated schedule for this litigation can be met.

II. SHIONOGI'S PROPOSED SEARCH TERMS ARE PROPORTIONATE

InterMune argues that it has sought to moderate the scope of discovery in this litigation, while Shionogi has insisted on an overly broad approach to discovery. *See* Opp. at 1:12-23. This is incorrect.

First, InterMune misstates the requirement for proportionality. The issue is not whether the parties' respective discovery burdens are proportionate to each other. Rather, the proper inquiry focuses on the time and expense of producing information and analyzes whether those factors are proportionate to the relevance and utility of the information sought. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii) (A court may limit discovery, where it determines that "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues."). Proportionality is defined by Rule 26(b)(2)(C)(iii), not by InterMune's requirement that the parties shoulder identical burdens. *See Oracle USA, Inc. v. SAP AG*, 264 F.R.D. 541, 543 (N.D. Cal. 2009) (explaining Rule 26(b)(2)'s proportionality requirement as "the burden or expense of the proposed discovery [in relation to] its likely benefit"); *see also Stanislaus Food Prods. Co. v. USS-POSCO Indus.*, 2012 WL 1940662, *4 (E.D. Cal. May 29, 2012) (identifying the text of Rule 26(b)(2)(C)(iii) as "the principle of proportionality").

The crux of the parties' disagreement regarding the scope of discovery is that they are not similarly situated. InterMune has voluminous information regarding Shionogi's clinical data and studies, because InterMune submitted Shionogi's studies in seeking marketing approval in the European Union and Shionogi assisted InterMune's regulatory filing. InterMune does not dispute that it requested and received study analyses, primary source data, and extensive assistance from Shionogi regarding Shionogi's studies in order to respond to inquiries from the EU regulators. Specifically, Shionogi worked with InterMune in responding to inquiries on the exact issues that InterMune now claims it will rely on to defend the case, such as alleged deficiencies with Shionogi's studies. Conversely, Shionogi has a relative dearth of information regarding InterMune's clinical studies and data because Shionogi did not rely on InterMune data in seeking regulatory approval for Shionogi's product. Shionogi's requests are proportionate to the needs of the case, the importance of the issues at stake, and the importance of the discovery in resolving the issues.

Further, Shionogi's approach to discovery is proportionate to the amount in controversy.

Contrary to InterMune's representations that the disputed royalties to date amount to less than $2 million (*see* Opp. at 8 fn. 3, 19 fn. 20), InterMune has published public data indicating that the European market for treatments for mild to moderate IPF is valued at between $2 to $3.5 billion.[2] Ritchey Reply Decl., Ex. 1 at p. 58. By that calculation, and applying InterMune's proxy of total sales (instead of net sales as defined in the contract), Shionogi stands to gain between $120 to $350 million in royalties from the sale of Esbriet based on its 6-10% royalty rate. Even assuming that the $2 million figure InterMune posits in its opposition is an appropriate calculation of royalties based on existing sales, the amount at stake is still far larger than InterMune suggests. InterMune's estimate represents 6% of European net sales of Esbriet in 2011 and through September of 2012. *See* Bornstein Decl., Ex. C at 49 and Ex. D at 4, 18. However, InterMune's recently released financials establish that it experienced a "significantly stronger than 9 percent" quarterly growth rate for the fourth quarter of 2012, thereby increasing the estimates in InterMune's opposition brief. Ritchey Reply Decl. Ex. 3. Additionally, because Esbriet is not currently sold in several of the EU countries in which InterMune plans to market the drug (Ritchey Reply Decl., Ex. 4), and the parties' agreement requires the payment of royalties for ten years, scaling from 6% in the first two calendar years to 10% in year five and beyond (ECF No. 18 at 2:24-27 (First Amended Complaint)), the $2 million royalty for 2011 and 2012 is likely to increase to tens of millions of dollars over the course of the agreement even under InterMune's projections. And, InterMune's public statements make clear that annual sales likely will increase following a multiyear introductory period, which further increases the amount in controversy. *See* Ritchey Reply Decl. Ex. 1 at 50 (recognizing that "success will be realized progressively" because "EU launch of new product takes 1-2 years from MAA approval").

Contrary to its assertions, InterMune has sought to disproportionately, and punitively, increase the scope of discovery for Shionogi. For example, the Collaboration Agreement defines the obligation to pay royalties according to how InterMune used Shionogi's data in its EU MAA. *Id.* at ¶ 18. InterMune's defense is based on a single, narrow theory—that notwithstanding how

[2] InterMune's estimates are based on analogizing the appropriate price of Esbriet to other drugs in the relevant jurisdictions.

InterMune used the data, Shionogi's internal documents will identify flaws with Shionogi's studies that InterMune overlooked when using them to support its bid for regulatory approval. From the outset, however, Shionogi agreed to produce its internal communications. Thus, InterMune's desire to broaden Shionogi's discovery obligations to include every document relating to Shionogi's clinical studies, the marketing approval process, and the resulting marketing of pirfenidone is emblematic of InterMune's punitive, tit-for-tat approach to discovery in this case. That approach does not comport with the rules and policies underlying the discovery process. *See Li v. A Perfect Day Franchise, Inc.*, 2011 WL 3895118, fn. 3 (N.D. Cal. Aug. 29, 2011) (explaining that "discovery is not conducted on a 'tit-for-tat' basis"). While InterMune's use of Shionogi data is at the heart of this dispute, how and why Shionogi may have used its own or InterMune's data is irrelevant to the claims and defenses at issue in this litigation, and it is not at issue in this motion to compel.

III. INTERMUNE'S BURDEN OBJECTION IS WAIVED AND UNSUPPORTED

A. InterMune's Delay Constitutes Waiver of its Burden Objection.

Shionogi and InterMune began meeting and conferring to discuss proposed search terms on November 5, 2012. Ritchey Decl. at Ex. 9. For the past two months, despite Shionogi's continued requests for data substantiating a burden objection (*Id.* at ¶¶ 29, 33 & Ex. 36), InterMune has failed to produce a meaningful hit report or provide other appropriate analysis to support its burden objection. *Id*. at Ex. 41. The discovery period is a third of the way complete, yet InterMune's opposition makes clear that it has just recently begun its review of documents.

"All discovery requests are a burden on the party who must respond thereto. Unless the task of producing or answering is unusual, undue or extraordinary, the general rule requires the entity answering or producing the documents to bear that burden." *Creighton St. Joseph Reg. Healthcare, LLC v. Lakeland Eng. Equip. Co.*, 2007 WL 4052064, *2 (D. Neb. Nov. 13, 2007) (citations and quotations omitted). Accordingly "[t]he party opposing a motion to compel has the burden of showing its objections are valid by providing specific explanations or factual support as to how each discovery request is improper." *Id.*; *see also Thompson v. Regional West Med. Ctr.*, 2007 WL 3232603, *2 (D. Neb. Oct. 31, 2007) ("The party resisting discovery has the burden to

show facts justifying its objection by demonstrating that the time or expense involved in responding to requested discovery is unduly burdensome."). The mere fact that complying with a discovery request will involve expense or consumption of time does not therefore render it unduly burdensome. Specific facts are needed to justify the objection. *See Jackson v. Montgomery Ward & Co.*, 173 F.R.D. 524, 529 (D. Nev. 1997). Objections that are not specifically justified in a timely fashion are waived. *See Thompson*, 2007 WL 3232603 at *2 (quoting Advisory Committee Notes to Rule 33 "objections must be specifically justified, and . . . unstated or untimely grounds for objection ordinarily are waived."); *see also Ramirez v. Co. of Los Angeles*, 231 F.R.D. 407, 409 (C.D. Cal. 2005) ("Most of defendant's objections are too general to merit consideration and are therefore waived.").

For two months, InterMune has failed to provide any meaningful analysis to support its burden objection. Without metrics relating to unique hit rates and responsiveness rates, InterMune's burden objection rests solely on speculation and unfounded assumptions. Because "[t]he party resisting discovery must show specifically how ... [requested discovery] is not relevant or . . . is overly broad, burdensome or oppressive[,]" *Creighton St.*, 2007 WL 4052064, *2 (citations omitted), InterMune has failed to sufficiently substantiate its burden. Specific facts, not conjecture, are required to establish the time, expense, and burden of production. *Id.* InterMune has failed to provide such specificity, and the Court should deem InterMune's objection waived. *See Ramirez*, 231 F.R.D. 409; *Thompson*, 2007 WL 3232603 at *2.

The two-month delay in providing any metrics to substantiate a burden objection belies InterMune's claims of diligence. When required to ascertain the burden of running broader search terms on its own document collection, Shionogi was able to generate preliminary hit report data within two weeks, despite the facts that Shionogi was required to translate search terms into Japanese to run the report (Ritchey Decl. ¶ 31), Shionogi's document collections are larger than InterMune's (Ritchey Decl. ¶ 39), and its analysis was conducted during the Christmas holiday. When InterMune first proposed broad search terms on December 13, Shionogi immediately began to analyze appropriate metrics (including unique hit rates and responsiveness rates). InterMune provided additional search terms to Shionogi on December 19, increasing the time Shionogi

needed to assess search term hits. Shionogi received preliminary hit report data on December 28 and informed InterMune that it did not intend to raise a burden objection, but reserved the right to do so as it continued to monitor search results. Ritchey Reply Decl. Ex. 2. The issue is not that InterMune has had insufficient time to substantiate its burden objection, it is that InterMune failed to act diligently to support that objection and therefore has waived it.

B. InterMune's Attempts to Limit Shionogi's Search Terms are Unreasonable and the Court Should Overrule the Proposed Modifications.

InterMune argues that the limiting language it proposes to Shionogi's search terms make them less burdensome. But InterMune ignores the internal safeguards the parties have built into the discovery process and fails to provide adequate data to substantiate its burden speculation.

Both parties have agreed to limit the number of custodians to twenty. ECF No. 30 at 3:23 (Joint CMC Statement). The parties have identified approximately twelve custodians each. These custodians were intimately involved in the data exchange and business relationship between the two companies. As a result, it is probable that these custodians will have largely responsive documents as compared to the broader population of either party's employees.

Moreover, InterMune's proposals to limit the disputed terms are based on assumptions rather than analytic metrics. *See* Opp. at 15-16. InterMune argues that the search term "option!" is too common a word and limitations are required. However, InterMune has not represented that it is collaborating with any other pharmaceutical company regarding the development or commercialization of pirfenidone; thus the only "option" InterMune would have exercised would be its option to license Shionogi's data. While Shionogi recognizes option is a common word, InterMune has not substantiated its burden objection by showing the approximate percentage of false positives the term "option!" might possibly generate among custodians associated with its Collaboration Agreement with Shionogi.

Similarly, replacing "transl!" with "Quintiles" or limiting "transl!" with "Quintiles" is unreasonable. While it is true that InterMune used a company named Quintiles to translate Shionogi data, it has not identified any data other than Shionogi's that was translated. Put another way, any references to translation likely concern Shionogi, but not all discussion of translating

Shionogi data is likely to reference Quintiles. InterMune's limitations, for example, disregard any discussion relating to the translation of Shionogi data prior to Quintiles being chosen as the entity to translate the data. Such an approach also fails to account for individuals who did not know the identity of Quintiles, or do not refer to the translations by reference to the company that translated them (*e.g.* "when do we expect the translations?" "have the translations been provided to the EU?"). InterMune has failed to cite any data supporting its argument that the term "transl!" results in false positive hits nor has it identified the number of unique hits attributable to "transl!" in relation to "Quintiles."

With regard to country names, Shionogi already has agreed to remove "United States" or its variants from the proposed search term list. But, it is unreasonable to assume that individuals at InterMune would discuss the regulatory process in particular jurisdictions by referencing only the regulatory agencies in those jurisdictions. Indeed, InterMune's own informational materials refer to its regulatory activities in various jurisdictions by country name, as opposed to regulatory agency. Ritchey Reply Decl. Ex. 1, pgs. 60-61. Moreover, specific countries, such as Germany, are important search terms. InterMune has represented that over 90% of its revenues flow from the sale of Esbriet in Germany. Ritchey Reply Ex. 3. InterMune has not identified the unique hit rates or responsiveness rates of documents that only contain a country search term, illustrating that the burden objection again rests on speculation and assumptions.

Lastly, InterMune's proposal to limit the search terms targeting pirfenidone and Esbriet forces the parties to design the discovery process based on information that already is known. Discovery is designed to allow the parties to learn information that they do not know. *See, e.g.,* Fed. R. Civ. P. 26(b)(1). InterMune's approach turns this principle on its head by asking Shionogi to speculate as to the terms InterMune used when discussing its products. Moreover, InterMune's EU MAA refers to its product by the trade name Esbriet, not by the clinical study names (*i.e.* PIPF-004 and PIPF-006), and it is reasonable to believe that post-marketing approval documents and communications would similarly refer to the product by its trade name. Such documents are relevant to Shionogi's damages, as well as the broader issue of liability. InterMune has not identified any data supporting its argument that the burden of including Esbriet

and pirfenidone as search terms within the limited custodian pool directly involved in this dispute is disproportionate to the importance of that discovery.

Because InterMune cannot substantiate its burden objection, and by extension cannot show the reasonableness of its proposed limitations, the Court should require InterMune to use Shionogi's proposed search terms, which were attached to the motion as Exhibit C.

IV. IN LIGHT OF INTERMUNE'S DELAY AND THE FAST-APPROACHING DISCOVERY DEADLINE, MORE THAN FOUR MONTHS TO SUBSTANTIALLY RESPOND TO DOCUMENT REQUESTS IS REASONABLE

InterMune's opposition focuses solely on the trial date, but that date is an improper measuring stick to determine the appropriate speed of discovery. Instead, the Court should look to when fact discovery closes—July 5, 2013. A full third of the discovery period has elapsed, and only six months remain to process and review documents, and to take depositions. While trial is not scheduled to commence until May 2014, the impending discovery cutoff requires swift action by InterMune. Requiring InterMune to substantially produce its documents by February 1 will have provided InterMune with four-and-a-half months to have collected, reviewed, and produced documents responsive to Shionogi's September 2012 requests.[3]

Additionally, the parties have agreed to a mediation on February 12, 2013. While InterMune has a large quantity of Shionogi data to prepare for the mediation, Shionogi has little information regarding InterMune's clinical studies, damages and the other information sought in Shionogi's discovery requests. If InterMune does not provide all or most of its documents to Shionogi by February 1, Shionogi cannot effectively prepare for the February 12, 2013 mediation.

Finally, the discovery period was structured to provide the parties with an opportunity to serve follow-up discovery after receiving and reviewing each other's initial responses. The fact that each party only identified twelve of its twenty allotted custodians makes this clear, as does

[3] In its opposition, InterMune contends that Shionogi's motion asks InterMune to advance the substantial completion of its document production "by just a few weeks—from mid-March 2013 to sometime in February or early March." Opp. at 1:6-8. This ignores that InterMune's "mid-March" estimate was based on running the narrow search terms and Shionogi's proposed schedule of "early March" was based on running the broader search terms. Shionogi's motion requests that, regardless of whether the broader search terms are run, review and production of documents containing the narrower search terms be completed by February 1, a full month-and-half before InterMune seeks to produce the documents.

InterMune's proposal to provide limited initial responses to Shionogi's damages discovery. *See* Ritchey Decl. ¶ 39, Ex. 42. Under InterMune's proposed schedule, Shionogi would have to review hundreds of thousands of pages of discovery, take depositions, and conclude all of its follow-up discovery in less than four months.

V. INTERMUNE SHOULD PROVIDE A RESPONSE TO INTERROGATORY NO. 2 TO NARROW THE DISPUTE AND ENABLE THE PARTIES TO EFFECTIVELY PREPARE FOR MEDIATION

Citing *In re eBay Seller Antitrust Litig.*, 2008 WL 5212170 (N.D. Cal. Dec. 11, 2008), InterMune miscasts Shionogi's Interrogatory No. 2, arguing that "any response would be premature by nature, since at least some of the facts that support InterMune's contention are solely in Shionogi's possession." Opp. at 21:13-15.

Shionogi's interrogatory requests that InterMune "[s]tate all facts supporting [its] contention that royalties are not due to Shionogi on [InterMune's] Net Sales of the Product in the European Union." Ritchey Decl. Ex. 2, at 6. Because InterMune has already made its decision that royalties are not due to Shionogi, the facts supporting its contention are already known to InterMune. And, the basis for InterMune's refusal to pay royalties *at the time of its decision not to pay* is relevant to Shionogi's breach of the implied covenant of good faith and fair dealing claim. *See Helus v. Equitable Life Assurance Society of the U.S.*, 309 F. Supp. 2d 1170, 1184 (N.D. Cal. 2004) (reasonableness of an insurer's actions at issue in bad faith denial of benefits claim is focused on what the insurer knew at the time of denial).

Accordingly, InterMune's response would not "be materially incomplete as soon as" Shionogi produces relevant documents. *See In re eBay*, 2008 WL 5212170, at *2. Instead, InterMune's early response will clarify the issues in the case, narrow the scope of the dispute, and help the parties prepare for the February 12, 2013 mediation. *See In re Convergent Technologies Sec. Litig.*, 108 F.R.D. 328, 339 (N.D. Cal. 1985). And, if InterMune concludes that additional facts obtained in discovery further support its position that it is not required to pay royalties to Shionogi, Rule 34 allows it to supplement its response. Accordingly, InterMune should provide an answer to the interrogatory at the outset, rather than waiting until the end of the discovery deadline, when much of the utility of the response will have passed. *See id.*

VI. CONCLUSION

For the reasons stated above, Shionogi respectfully requests that the Court grant Shionogi's Motion to Compel.

Dated: January 4, 2013

Respectfully submitted,

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